

REMARKS

In the Decision on Appeal, decided December 10, 2007 (hereinafter “Decision”), the Board affirmed the rejection of claims 1-14 under 35 USC § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229) (hereinafter “Chu”) in view of Kanno (U.S. Patent No. 4,629,455) (hereinafter “Kanno”), but noted that the elements of Applicants’ claims are only met by such references when a separate connector part is coupled between a first and second syringe. (See, e.g., Decision at 2 and 10.)

Claims 1, 3-6, 9-12 and 14 are currently amended and fully supported by the application as filed, such as at pp. 2-3, 5 and FIGS. 3-5. Claim 2 is cancelled without prejudice or disclaimer. Claims 15-24 are new and fully supported by the application as filed, such as at pp. 2-3, 5, 11-18 and FIGS. 3-5. As a result, claims 1 and 3-24 are pending and responded to in this application.

Applicants hereby respectfully request further examination and reconsideration of this application in view of the foregoing claim amendments and following remarks.

Request for Interview

1. Prior to the Office issuing any subsequent communications, Applicants respectfully request a telephonic interview at the Examiner’s convenience. Applicants’ attorney Gregory W. Smock can be reached by telephone at (612) 373-6956.

§103 Rejection of the Claims

2. Claims 1-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu in view of Kanno. Applicants respectfully request reversal of this rejection on the ground that there is no *prima facie* case of obviousness for the claims, as amended.

Claim 1:

Applicants submit that the proposed combination of Chu and Kanno is improper and fails to establish all elements recited in Applicants’ claims for at least the following reasons. First, the cited references, neither alone nor in combination, teach or suggest all of Applicants’ claimed

elements. Claim 1, for example, presently recites a coupling syringe system comprising a first syringe including a first tip with an integral male end portion and a second syringe including a second tip with an integral female end portion. The integral male end portion of the first syringe and the integral female end portion of the second syringe are configured to directly couple to one another thereby forming a single attachment site between the first and second syringes. In other words, Applicants' claimed syringe system forecloses the use of separate connection parts to form either the first or second syringe. In contrast, Chu recites a separate connection part disposable between a first and second syringe to connect the same at two different attachment sites. For instance, Chu states:

The two syringes are connected by means of a relatively simple adapter system. First adapter 42 at substantially closed end 18 of the first syringe 12 is joined to second adapter 44 at substantially closed end 24 of the second syringe 14During admixture, the adapters are joined by connector means 50.

(Chu at col. 4, ll. 44-51; *see also*, col. 3, ll. 35-37; col. 6, ll. 19-20 and 45-47; and FIG.

2)(emphasis added.) Kanno further fails to satisfy the foregoing deficiencies of Chu. According to the MPEP § 2142, the prior art reference(s) must teach or suggest all of the claim elements. Because Chu and Kanno, alone or in combination, fail in this regard, Applicants respectfully request reconsideration and withdrawal of this basis of rejection of claim 1.

Second, the separate connection part of Chu teaches away from the integral connection configuration claimed by Applicants. More specifically, the Chu syringe system when connected to the intermediately disposed separate connector part 50 structurally and functionally differs from the claimed syringes including the integral connection configuration. As one example, the invention of claim 1 provides a solution to Applicants' newly recognized problem of mixing systems including two syringes with a separate connection part (i.e., a syringe system similar to Chu). Such problems include plug flow of contents in the separate connection part and additional leakage opportunities via more than one attachment site. For instance, Applicants state in their application:

[An] independent coupling means [] provides a space where there is very little agitation due to plug flow of the contents. The contents, therefore, do not mix well. Additionally, when the syringes are uncoupled (i.e., disengaged), the contents have to be aspirated out of the independent coupling means or they will be lost. In addition, the independent

coupling means must be removed and discarded before attaching a needed to the delivery or injection syringe.

(Application at p. 2, ll. 3-9)(emphasis added).

The present invention provides a syringe system wherein components of a composition can be easily mixed by the end user without losing a significant amount of mixed composition during the mixing process and wherein the mixed composition can be easily and rapidly administered to a patient. The syringe system has a relatively few number of interconnecting parts, to minimize human error and to minimize sample loss.

Additionally, the syringe system effectively mixes the contents located therein without sample loss, such that it can be approved by the FDA when used with drugs that must be administered in a known, discrete and precise amount (e.g., leuprolide acetate).

(Application at p. 4, ll. 12-20)(emphasis added). According to the Federal Circuit, motivation to combine references is lacking when the reference(s) teach away from the claimed combination. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986)(A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered). Because Chu teaches away from Applicants' claimed combination, the asserted combination of references is improper and fails to establish all elements recited in claim 1.

Third, as alluded to above, Chu contains a different structure from Applicants' claimed combination. To this end, Applicants' would like to direct the Office's attention to the Federal Circuit's holding and summarized facts in *Warminster Fiberglass Co. v. Delta Fiberglass Structures, Inc.*:

In this case, the inventors specifically claimed a scum baffle that was integral with the hood. Because we interpret the term integral to mean "structurally related," we cannot consider the accused device, in which the scum baffle and hood are physically separated, to be the equivalent of the claimed invention without reading out the term "integral."

42 USPQ.2d 1154 (Fed. Cir. 1996)(unpublished). Similar to the facts of *Warminster*, Applicants' claimed combination includes connection components integral with a first and second syringe. In contrast, the cited reference – Chu – recites two syringes and a physically separate connector part. Because Chu recites a different structure from Applicants' claimed combination, the asserted combination of references is improper and fails to establish all elements recited in claim 1.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this basis of rejection of claim 1. Claims 3-20 are dependent on claim 1 and are patentable over the cited references for the reasons remarked above, in addition to the elements in such claims.

Claims 9 and 12:

Additionally, regarding claims 9 and 12, Applicants submit the Office's asserted motivation for combining Chu and Kanno runs afoul of the Federal Circuit's holding in *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 53 U.S.P.Q.2d 15080 (Fed. Cir.), *cert. denied*, 530 U.S. 1238 (2000). According to the Office, it would have been obvious to one having ordinary skill in the art to combine Chu and Kanno to provide a male and female connection alternative that can be joined firmly with high reliability. (Office Action at 9-10; *see also* Decision at 12.) Applicants submit that the term "alternative" infers that Chu, alone, recites a suitable connection mechanism in which a male and female element can be firmly joined. To this end, the Federal Circuit has previously held "[t]rade-offs often concern what is feasible, not what is, on balance, desirable. Motivation to combine requires the latter." *Winner Int'l Royalty Corp.*, 53 U.S.P.Q.2d 15080.

Further, the Office appears to inherently recognize it is improper to combine Chu and Kanno, as Kanno teaches away from combination with Chu. For instance, the Decision states:

As pointed out by the Examiner, Kanno describes the disadvantages of a non-rotatable locking ring in the prior art [and as recited by Chu].

(Decision at 4-5 and 12-13.) As remarked above, the Federal Circuit has previously held that motivation to combine references is lacking when the references teach away from the claimed combination. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986) Because there is no objective motivational evidence of record for the Office Action's assertion that it would have been obvious to combine the teachings of Chu and Kanno for connection purposes, Applicants respectfully request withdrawal of this basis of rejection of claims 9 and 12.

Claim 21:

Applicants submit that the proposed combination of Chu and Kanno is improper and fails to establish all elements recited in Applicants' claims. Claim 21, for example, presently recites a coupling syringe system consisting of a first syringe including a first tip with an integral male end portion and a second syringe including a second tip with an integral female end portion. The integral male end portion of the first syringe and the integral female end portion of the second syringe are configured to directly couple to one another. To this end, Applicants' hereby incorporate by reference the relevant remarks asserted above with respect to claim 1 (i.e., Chu and Kanno fail to teach or suggest all elements recited in Applicants' claim 21; the separate connection part of Chu teaches away from the integral connection configuration claimed by Applicants; and Chu contains a different structure from Applicants' claimed combination). Further, Applicants submit that claim 21 recites a coupling syringe system "consisting of," not making suitable the existence or use of the additional separate connection element of Chu, for example.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this basis of rejection of claim 21. Claims 22-24 are dependent on claim 21 and are patentable over the cited references for the reasons remarked above, in addition to the elements in such claims.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited and encouraged to telephone Applicants' attorney Gregory W. Smock at (612) 373-6956 or Gary J. Speier at (612) 359-3261 to facilitate prosecution of this application.

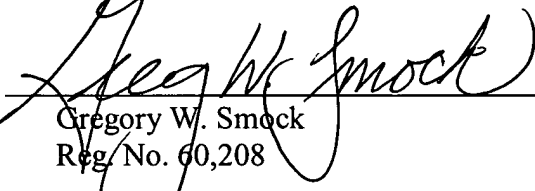
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Respectfully submitted,

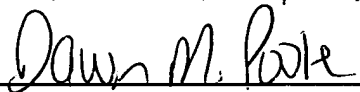
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Date FEBRUARY 11, 2008

By


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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 11th day of February, 2008.



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